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KILLWORTH GOTTMAN HAGAN & SCHAEFF
ONE DAYTON CENTRE
ONE SOUTH MAIN STREET SUITE 500
DAYTON OH 45402-2023

DUBOIS, P	EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/163,778	Applicant(s) Lepine
	Examiner Philip DuBois	Group Art Unit 1761

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-14* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kakade (U.S. Patent 4,614,653) and Oftedal (Lactation in the Dog: Milk Composition and Intake by Puppies, pg. 807).

. Kakade teaches a milk replacer designed for the feeding of monogastric animals. The milk replacer comprises protein, fat, carbohydrates, lactose, and whey (U.S. Patent 4,614,653, col 1, lines 55-65). Kakade teaches that a milk replacer can contain 10-16% total protein with total solids content of from 50 to 75% (U.S. Patent 4,614,653, col 1, lines 60-63). Thus, on a dry matter basis, Kakade teaches that the amount of protein can vary from 13.3% to 32%.

Kakade also teaches that 1 to 25% oil fat or oil can be used (U.S. Patent 4,614,653, col 1, lines 65-68). On a dry matter basis this corresponds to 1.33 to 50.0% of the total milk replacer.

Kakade teaches that the total sugar/carbohydrate content of the product ranges from 10 to 45% (U.S. Patent 4,614,653, col 2, lines 22 -28). However, on a dry solids basis, this would

correspond to a range of 13.33% to 90% of the milk replacer. Furthermore, the sugar or carbohydrate content comprises a variety of components including lactose. (US Patent 4,614,653, col 2, lines 27-30). The lactose can be 10 to 35 percent of the total sugar content in the milk replacer (U.S. Patent 4,614,653, col 2, line 28).

Kakade teaches that lactose can be added to the formula. The carbohydrate portion can contain 10 to 35% lactose (U.S. Patent 4,614,653, col 2, lines 27-30). It would have been obvious to one of ordinary skill in the art to optimize the amount of lactose in the product.

Although Kakade teaches that protein can be added to a milk replacer, Kakade does not teach that the protein percentage should range from 35-45% percent.

Oftedal teaches the fat, protein, and carbohydrate composition of canine milk. In Table 4, Oftedal shows the results of a variety of studies on the protein content of canine milk. The studies teach that the protein levels may vary but several of the studies clearly teach that the protein level can fall within a range of 35-45% on a dry matter basis. The results of Ssubotina and Deniges both show that the protein levels on a dry matter basis are approximately 42% and 38%, respectively Oftedal (Lactation in the Dog: Milk Composition and Intake by Puppies, Table, pg. 807).

Thus, it would have been obvious to one of ordinary skill in the art to develop a canine milk with a protein range of 35-45%, since natural canine milk contains protein levels that can vary within this range, as taught by Oftedal.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the percentages of the fat, protein and carbohydrate.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oftedal and Kakade as applied to claims 1, 3-5 and 9 above, and further in view of Irvine et al (U.S. Patent 4,692,338).

Oftedal and Kakade are being applied for the reasons noted above. However, the above references do not teach that casein can be used in a milk substitute. Irvine et al (Irvine) teaches that casein and whey can be used in a ratio to optimize the effects of a milk substitute. In example 1, Irvine teaches that casein and whey can be used in a milk substitute at levels of 17% and 6%. This is a casein to whey ratio of approximately 74:26. (U.S. Patent 4,692,338, col 3, lines 55-60). It would have been obvious to one of ordinary skill in the art to optimize the ratio of casein to whey.

Thus, it would have been obvious to one of ordinary skill in the art to use casein and whey in a milk substitute, since the casein can act as an anticoagulant and the whey offers a nutritious source of protein, as taught by Irvine et al.

4. Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oftedal and Kakade as applied to claim 1, 3-5 and 9 above, and further in view of Gil et al (U.S. Patent 5,709,088).

Oftedal and Kakade are being applied for the reasons noted above. However, they do not teach that arachidonic and docosahexaenoic acid can be added to a milk substitute. Gil et al (Gil)

teaches that arachidonic and docosahexaenoic acids are fatty acids which can be placed in an infant formula. (U.S. Patent 5,709, 088, abstract).

Thus, it would have been obvious to one of ordinary skill in the art to add arachiodonic and docosahexaenoic acid to a formula, since they improve infant development, as taught by Gil et al.

5. Claim 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kakade, Oftedal, and Gil as applied to claims 6 and 14 above, and further in view of Traitler et al (U.S. Patent 4,938,984).

Kakade, Oftedal, and Gil are being applied for the reasons noted above. However, the above references do not teach that omega fatty acids and trans fatty acids can used to supplement food compositions.

Although not noted above, Gil teaches that palmitic, stearic, oleic, linoleic, alpha-linolenic, arachidonic and docosahexaenoic fatty acids can be added to an infant formula. Gil states, "The present inventions fat mixtures possess adequate levels of phospholipids and an adequate relationship between oleic acid, linoleic acid and alpha-linolenic acid as well as adequate levels of long chain polyunsaturated fatty acids of both the n6 and n3 series. In addition, the fat mixtures of the present invention possess and adequate ratio of arachidonic acid (20:4n6) to docosahexaenoic acid (22:6n3)." (US Patent 5,709,888, col 7, lines 4-10).

Gil also teaches that palmitic and stearic fatty acids are present in milk and could be additives to a milk substitute. The palmitic acid and stearic acid can make up to 25 % and 7% percent of the total fatty acids present in milk, respectively (U.S. Patent 5,709,888, col 7, lines 25-28).

Traitler teaches that omega 3, omega 6, and trans fatty acids can be added to a food composition. Traitler teaches that the fatty acids can be supplemented in the food composition by adding an oil extract that contains the necessary fatty acids. (U.S. Patent 4,938,984, abstract). Traitler teaches that these extracted oils contain the fatty acids. The oils contain cis, trans and omega 3 and omega 6 oil (U.S. Patent 4,938,984, col 2, lines 47-59).

The fatty acids of the claimed invention are all known food additives. It would have been obvious to one of ordinary skill in the art to optimize the amount of fatty acids present in a milk formula. Thus, it would have been obvious to one of ordinary skill in the art to add fatty acids to a substitute milk, since the fatty acids are important components in membrane lipids, as taught by Traitler.

6. Claim 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kakade and Oftedal as applied to claims 1, 3-5 and 9 above, and further in view of Kinumaki et al (U.S. Patent 4,294,856).

Kakade and Oftedal are being applied for the reasons noted above. However, they do not teach that amino acids can be added to a milk substitute product for infant animals.

Kinumaki et al (Kinumaki) teaches that amino acids can be added to an infant formula (U.S. Patent 4,294,856, col 14, lines 1-25). Thus, it would have been obvious to one of ordinary skill in the art to optimize the amount of supplemental amino acids in the formula. Amino acids are essential nutrients. Some amino acids may be synthesized by the organism itself or must be present in the diet.

Thus, it would have been obvious to one of ordinary skill in the art to incorporate amino acids into an animal formula, since amino acids are important nutrients, as taught by Kinumaki.

7. Claim 10 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Kakade and Oftedal as applied to claim 1, 3-5 and 9 above, and further in view of Fujimori (U.S. Patent 5,294,458).

Kakade and Oftedal are being applied for the reasons noted above. However, they do not teach that fructooligosaccharide can be added to an infant formula. Fujimori teaches that fructooligosaccharide can be added to a pet food. Fujimori teaches that fructooligosaccharide is placed in pet food to metabolize the intestinal flora (U.S. Patent 5,294,458, col 2, lines 40-48).

Thus, it would have been obvious to one of ordinary skill in the art to place fructooligosaccharide in a pet food, since it is well know that fructooligosaccharide aids the excretory system, as taught by Fujimori.

Finally, Applicants' attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered on point in the fact situation of the instant case, and wherein the Court stated on page 234 as follows:

> This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients which produces a new, unexpected, and useful function. *In re Benjamin D. White*, 17 C.C.P.A (Patents) 956, 39 F.2d 974, 5 USPQ 267; *In re Mason et al.*, 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 USPQ 221.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 3-5 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,792,501 in view of Kakade and Oftedal.

Although the claims are not identical, they are not patentably distinct from each other because the claims of the patent application describe similar limitations of a composition. The difference between the claimed invention of U.S. application number 09/163,778 and the claims of U.S. Patent 5,792,501 is the intended use. The same composition is being used for use in a canine milk replacer and a feline milk replacer.

The noted references are being used for the same reasons stated above. Thus, it would have been obvious to use the same limitations of a feline milk replacer composition in a canine

milk replacer composition, since the composition produces enhanced growth of feline and canine young, as taught by Kakade and Oftedal.

10. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,792,501 in view of Oftedal, Kakade and Irvine.

Although the claims are not identical, they are not patentably distinct from each other because the claims of the patent application describe similar limitations of a composition. The difference between the claimed invention of U.S. application number 09/163,778 and the claims of U.S. Patent 5,792,501 is the intended use. The same composition is being used for use in a canine milk replacer and a feline milk replacer.

Kakade, Oftedal and Irvine are being used for the same reasons stated above. Thus, it would have been obvious to use the same limitations of a feline milk replacer composition in a canine milk replacer composition, since the composition produces enhanced growth of feline and canine young, as taught by Kakade, Oftedal and Irvine.

11. Claims 6 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,792,501 in view of Oftedal, Kakade and Gil.

Although the claims are not identical, they are not patentably distinct from each other because the claims of the patent application describe similar limitations of a composition. The difference between the claimed invention of U.S. application number 09/163,778 and the claims

of U.S. Patent 5,792,501 is the intended use. The same composition is being used for use in a canine milk replacer and a feline milk replacer.

Kakade, Oftedal and Gil are being used for the same reasons stated above. Thus, it would have been obvious to use the same limitations of a feline milk replacer composition in a canine milk replacer composition, since the composition produces enhanced growth of feline and canine young, as taught by Kakade, Oftedal and Gil.

12. Claims 7 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-20 of U.S. Patent No. 5,792,501 in view of Kakade, Oftedal, Gil and Traitler.

Although the claims are not identical, they are not patentably distinct from each other because the claims of the patent application describe similar limitations of a composition. The difference between the claimed invention of U.S. application number 09/163,778 and the claims of U.S. Patent 5,792,501 is the intended use. The same composition is being used for use in a canine milk replacer and a feline milk replacer.

Kakade, Gil, Trailter and Oftedal are being used for the same reasons stated above. Thus, it would have been obvious to use the same limitations of a feline milk replacer composition in a canine milk replacer composition, since the composition produces enhanced growth of feline and canine young, as taught by Kakade, Gil, Traitler and Oftedal.

13. Claims 8 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,792,501 in view of Kakade, Oftedal and Kinumaki.

Although the claims are not identical, they are not patentably distinct from each other because the claims of the patent application describe similar limitations of a composition. The difference between the claimed invention of U.S. application number 09/163,778 and the claims of U.S. Patent 5,792,501 is the intended use. The same composition is being used for use in a canine milk replacer and a feline milk replacer.

Kakade, Oftedal and Kinumaki are being used for the same reasons stated above. Thus, it would have been obvious to use the same limitations of a feline milk replacer composition in a canine milk replacer composition, since the composition produces enhanced growth of feline and canine young, as taught by Kakade, Oftedal and Kinumaki.

14. Claims 10 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. U.S. Patent No. 5,792,501 in view of Kakade, Oftedal, and Fujimori.

Although the claims are not identical, they are not patentably distinct from each other because the claims of the patent application describe similar limitations of a composition. The difference between the claimed invention of U.S. application number 09/163,778 and the claims of U.S. Patent 5,792,501 is the intended use. The same composition is being used for use in a canine milk replacer and a feline milk replacer.

Kakade, Oftedal and Fujimori are being used for the same reasons stated above. Thus, it would have been obvious to use the same limitations of a feline milk replacer composition in a canine milk replacer composition, since the composition produces enhanced growth of feline and canine young, as taught by Kakade and Oftedal.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip DuBois whose telephone number is (703) 305-0508. The examiner can normally be reached on Monday through Friday from 8:00 to 5:30.The examiner is not in the office the second and fourth Fridays of each month.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Lacey, can be reached on (703)-308-3535. The **fax phone number** for this Group is (703)-305-3601.

18. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Philip A. DuBois

June 21, 1999

David Lacey
Supervisory Patent Examiner
Technology Center 1700
6/24/99